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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/795,933	03/08/2004	Jan Zavada	D-0021.2-2	2689

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LEONA L. LAUDER
235 MONTGOMERY STREET, SUITE 1026
SAN FRANCISCO, CA 94104-0332

EXAMINER	
SHIN, DANA H	

ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
08/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

deeopat@pacbell.net
LLLpat@pacbell.net
jharland@pacbell.net

Office Action Summary	Application No.	Applicant(s)	
	10/795,933	ZAVADA ET AL.	
	Examiner	Art Unit	
	DANA SHIN	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-35 and 39-55* is/are pending in the application.

4a) Of the above claim(s) *41-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-35,39,40 and 53-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

This Office action is in response to the communications filed on July 2, 2008.

Currently, claims 31-35, 39-40, and 53-55 are under examination on the merits.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Priority

The benefit of an earlier filing date remains denied for claims 31-35, 39-40, and 53-55 for the reasons of record as set forth in the Office action mailed on March 4, 2008 and for the reasons stated below.

Applicant's arguments filed on July 2, 2008 have been fully considered but they are not persuasive. Applicant argues that "implicit" disclosure provides an adequate written description for the claimed vector comprising an antisense oligonucleotide because one skilled in the art

would reasonably "think" that the inventors were in possession of the instantly claimed invention and therefore "explicit" or "literal" disclosure of the structure of the claimed invention is not required. Applicant's such assertion is based on the fact that inventors discovered the MN gene and MN antisense oligonucleotides. The disclosure of isolated MN gene and use of MN antisense oligonucleotides in prior-filed application has not been disputed by the Office. In the instant case, however, neither the MN gene nor the MN antisense oligonucleotides are being claimed. The fact that present inventors are granted patents for the MN gene and use of MN antisense oligonucleotides such as in US Patent 6,774,117 does not warrant that the disclosure of US Patent 6,774,117 reasonably conveys to one skilled in the art to conclude or automatically assume that the inventors were indeed in possession of the claimed vector system as of the filing date of US Patent 6,774,117, nor does it guarantee that the inventors are automatically entitled to patent protection for anything and everything that has to do with MN antisense oligonucleotides.

Note that to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention, or by showing description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.. See MPEP§2163. However, in the instant case, there is not even an

implicit suggestion that the MN antisense oligonucleotides disclosed in 6,774,117 are meant to be inserted into an expression vector or that inventors contemplated making the claimed vector system, let alone a detailed description of the claimed invention with all of its limitations. The only explicit and implicit support as far as the antisense "vector" system is concerned within the meaning of 35 U.S.C. 112, first paragraph is a vector comprising an antisense sequence of MN cDNA. See column 26. Even within the disclosure of antisense vector system, there is no indication, direct or indirect, that a vector construct comprising an MN promoter operably linked to an MN antisense oligonucleotide is envisioned by the inventors, let alone adequate support for the "possession" of such vector construct (e.g., showing of actual reduction to practice, disclosure of drawings, disclosure of complete structure, disclosure of structure/function correlation). See also *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004), wherein the Court expressed that an adequate written description of a chemical invention such as the claimed antisense vector structure also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed.

Applicant asserts that there is a body of evidence showing that the inventors were indeed in possession of the instantly claimed invention. However, applicant points to various passages to show separate and independent disclosures for preferable MN antisense oligonucleotides of 19-29 nucleotides in length complementary to the 5' end of MN cDNA, vectors for recombinant production of MN proteins/polypeptides, and an antisense vector comprising an antisense MN cDNA. That is, applicant has failed to show that the claimed invention as a whole is indeed adequately described in the disclosure of 6,774,117. Applicant also argues that the instantly

claimed antisense oligonucleotide vector structure is properly disclosed in the instant specification via incorporation by reference. Specifically, applicant argues that the 1991 Mercola review article is incorporated in the instant specification. First, the alleged "incorporation by reference" of the Mercola article is improper. Apparently, the instantly claimed antisense oligonucleotide vector is an "essential material" for the claimed invention. However, the Mercola article is a non-patent literature article, and the "essential material" may be incorporated by reference "only by way of an incorporation by reference to a U.S. Patent or U.S. patent application publication". See 37 CFR 1.57(c)(1). Further, the alleged incorporation by reference is improper because the Mercola article is not clearly identified or intended to be incorporated by using the root words "incorporate by reference". See 37 CFR 1.57(b)(1)(2). Even if the Mercola article were a properly incorporated reference, it does not teach anything about a vector structure containing an antisense oligonucleotide of 19-29 nucleotides in length. At best, Mercola teaches a vector comprising an antisense oligonucleotide of 40 nucleotides in length. Applicant also agues that the declaration under 37 CFR 1.132 submitted on January 4, 2007 provides further evidence that the inventors were in possession of the claimed invention. Contrary to applicant's argument, the declaration does not explicitly disclose nor implicitly suggest anything about a vector expressing an MN antisense oligonucleotide of 19-29 nucleotides in length. The content of the declaration is a replication or restatement of the working examples disclosed in the instant specification, which include transfection experiments comprising a vector expressing a full-length MN antisense cDNA or a full-length MN sense cDNA. Hence, the declaration does not provide any additional information besides the disclosure of the instant specification, and furthermore, it fails to provide any factual evidence that the inventors were in possession of the

claimed invention at the time the of filing of US Patent 6,774,117. Lastly, applicant argues that the claimed invention is fully supported by the original claims filed in the US Patent 6,774,117, wherein original claim 6 was directed to a vector "containing at least fifty nucleotides" complementary to the MN cDNA. Again, the instantly claimed invention is directed to a vector expressing an MN antisense oligonucleotide, wherein the antisense oligonucleotide is SEQ ID NO:3 (29 nucleotides) or SEQ ID NO:4 (19 nucleotides), or SEQ ID NO:7 (25 nucleotides). In addition, the term "antisense oligonucleotide" in the instant specification is used only to refer to a single-stranded antisense nucleic acid with a length limitation of 29mer, 19mer, or 25mer, each corresponding to SEQ ID NO:3 (or "ODN1"), SEQ ID NO:4 (or "ODN2"), and SEQ ID NO:7, respectively. Hence, the original claim for a vector expressing an antisense oligonucleotide of 50 or more nucleotides in length provides no adequate support and description for the instantly claimed vector expressing an antisense oligonucleotide that is 29 or fewer nucleotides in length in the manner provided by the first paragraph of 35 U.S.C. 112.

In view of the foregoing, it is concluded that there is neither implicit nor explicit description for the claimed invention, which would lead one skilled in the art to reasonably conclud that the inventors were in possession of an antisense vector structure other than the described antisense vector structure comprising an antisense, full-length MN cDNA, or a nucleotide sequence of 50 or more nucleotides that are complementary to MN cDNA at the time of filing of US 6,774,117 in June 15, 1994. Hence, the earliest effective filing date for the claims at issue in the instant case remains as the filing date of the instant application, March 8, 2004.

Claim Rejections - 35 USC § 103

Claims 31-35, 39-40, and 53-55 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zavada et al. in view of Benedetti et al. for the reasons of record as set forth in the Office action mailed on March 4, 2008 and for the reasons stated below.

Applicant's arguments filed on June 18, 2008 have been fully considered but they are not persuasive. Applicant argues that Zavada et al. U.S. Patent (issued on April 18, 2000) cannot be prior art because the priority of the instantly claimed invention is at least the filing date of U.S. Patent 6,774,117. As stated and detailed above, the priority of the instantly claimed invention is not entitled to the filing date of U.S. Patent 6,774,117, and the effective filing date for the claimed invention is March 8, 2004. Hence, Zavada et al. U.S. Patent is a proper prior art reference and therefore this rejection is maintained.

Conclusion

No claim is allowed.

This application contains claims 41-52 drawn to an invention nonelected with traverse in the reply filed on March 16, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, from 7am-3:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

/J. E. Angell/
Primary Examiner, Art Unit 1635